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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,056	05/22/2006	Peter Joseph Ayre	115427.00004	3676
72535 7590 10/01/2007 MCCARTER & ENGLISH, LLP STAMFORD OFFICE FINANCIAL CENTRE, SUITE 304A 695 EAST MAIN STREET STAMFORD, CT 06901-2138			EXAMINER SAIDI, AZADEH	
			ART UNIT 3735	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/565,056

Applicant(s)

AYRE ET AL.

Examiner

Anita Saidi

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 01/17/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3735

## **DETAILED ACTION**

### ***Oath/Declaration***

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites that the cuff is positioned to contact the outer surface of a tubular body and that the cuff is integrally formed within a cannula. It is unclear whether the tubular body is also integrated inside the cannula, however there is no support for this in the specification. It appears claim 1 inappropriately blends two different embodiments of the disclosed invention, as the cuff is not disclosed as

Art Unit: 3735

contacting the outer surface of a tubular body in the embodiments wherein the cuff is embedded in the cannula.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said heart" in line 2. There is insufficient antecedent basis for this limitation in the claim. The limitation "said heart" has not been mentioned in any of the previous claims, therefore it is not clear what heart has been claimed.

Claim 8 recites the limitation "said blood pump" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no blood pump recited in claims 1 or 8 prior to this recitation.

Claim 9 recites the limitation "said implantable blood pump" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. There is no implantable blood pump recited in the claims prior to this recitation.

#### ***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 3735

7. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites that “a cuff positioned to contact the outer surface of a tubular body”. According to several disclosed embodiments of the instant invention, this recites a positive relationship to the human body, such as an aorta or a ventricle. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend claim 1 to recite that --the cuff is adapted to contact the outer surface of a tubular body --.

*Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1,2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,240,207 to Barker et al (Hereinafter “Barker”).

In reference to claims 1 and 2:

Baker teaches an implantable device (Fig. 3 of Barker), including: a cuff (flexible tube 10 of Barker) positioned to contact the outer surface (8 in Fig. 3 of Barker) of a tubular body (artery 7 of Barker) carrying blood; and at least one sensor (pressure transducer 13 of Barker) which measures blood pressure encapsulated within said cuff (Col. 3, lines 41-70 of Barker), wherein said cuff is integrally

Art Unit: 3735

formed within a cannula (rigid ring 11, Fig. 1 of Barker). As it is shown in Figs. 1-3 the cuff does not substantially occlude or affect the flow of blood within the artery.

In reference to claim 6:

The cuff comprises polyethylene terephthalate (Col. 2, lines 33-40 of Barker).

*Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker in view of US 5,807,258 to Cimochoowski et al (Hereinafter "Cimochoowski").

In reference to claims 3 and 4:

Barker teaches, all of the claim limitations, see the rejections above.

However, Barker fails to teach that:

The device includes at least two sensors and the sensors are aligned axially in respect to the tubular body.

Cimochoowski teaches:

Ultrasonic sensors (242a, 242b in Fig. 20A of Cimochoowski) for monitoring the condition of a vascular graft. The sensors monitor

Art Unit: 3735

the velocity and flow of blood and blood pressure (Col. 24, lines 7-24 of Cimochoowski) through the graft (Abstract of Cimochoowski).

The pressure sensor can be aligned axially (transducers 242a and 242b in Fig. 20A ) or on opposite sides of the graft (transducers 174a and 174b in Fig. 14).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have replaced the pressure sensor of Baker with similar ultrasound sensors of Cimochoowski in order to measure the blood flow and pressure within a graft.

11. Claims 5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker in view of US 5,693,091 to Larson, Jr et al (Hereinafter "Larson").

In reference to claims 5 and 7-9:

Barker teaches, all of the claim limitations, see the rejection above.

However, Barker fails to teach that:

The cuff cooperates and is connected to a controller that determines the pumping state of a heart from changes in pressure, and the blood pressure is used in a feed back mechanism to control the pumping speed of the blood pump, the feed back mechanism including a controller, which adjusts pumping speed to minimize under-pumping and over-pumping by the implantable blood pump.

Art Unit: 3735

Larson teaches:

A surgically implantable reciprocating pump (module 34) that employs a check valve as the piston, which is driven by a permanent magnet linear electric motor to assist either side of the natural heart. The pump is implanted in the aorta or pulmonary artery using vascular attachment cuffs (4 of Larson) such as flexible cuffs for suturing at each end with the pump output directly in line with the artery (Abstract of Larson). A controller (50 of Larson) can optionally incorporate a rate responsive algorithm which uses RMS input from a pressure transducer on the outside of the controller enclosure. The RMS input measures the amplitude of intra-anatomical pressure waves or some other indication of the patient's level of physical activity. This algorithm may provide for a programmable lower heart rate limit (e.g., 50-80 beats per minute) and upper heart rate limit (e.g., 110-140 beats per minute) between which the controller may adjust the TAH rate in response to the patient's level of physical activity. The TAH may optionally incorporate intra-aortic and intra-pulmonary pressure transducers which provide feedback to the controller used to regulate the patient's systolic and diastolic pressures between pre-programmed limits in response to the patient's level of physical activity. The TAH controller monitors total current to the linear motor for detection of indications that venous

collapse has occurred due to excessively low inlet pressure. Upon detection of venous collapse, the controller slows or reverses direction of the piston-valve to correct this condition (Col. 23, lines 7-37 of Larson).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used the pressure sensor attached to the cuff of Barker with an artificial pump and the pressure sensor similar to the one used in the artificial heart for monitoring blood flow of Larson, in order to monitor the heart's pumping speed and if necessary control the artificial pump in order to avoid collapse of the heart or the arteries.

### *Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,190,057 to Hill et al discloses a device for determining the patency of a blood vessel. US 4,600,855 to Strachan discloses an apparatus for measuring bodily fluid pressure within a conduit. US 5,658,318 to Stroetmann et al discloses a method and apparatus for detecting a state of imminent cardiac arrhythmia. US 2003/0023255 to Miles et al discloses a cannula in cooperation with an artificial pump. US 6,974,436 to Aboul Hosn et al discloses an integrated pump and cannula system.


Art Unit: 3735

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is 571-270-3001. The examiner can normally be reached on Monday-Thursday 9:30 am - 7:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AS  
9/26/2007

  
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